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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,180	10/28/2003	William Travis Young	33386	2749

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DORSEY & WHITNEY, LLP
INTELLECTUAL PROPERTY DEPARTMENT
370 SEVENTEENTH STREET
SUITE 4700
DENVER, CO 80202-5647

EXAMINER

CHORBAJI, MONZER R

ART UNIT PAPER NUMBER

1744

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,180

Applicant(s)

YOUNG ET AL.

Examiner

MONZER R. CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This final action is in response to the Amendment received on 07/11/2006

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Popescu et al (U.S.P.N. 5,464,580).

Regarding claim 1, Popescu teaches the following steps in ethylene sterilization of medical items (col.1, lines 6-11): conditioning items by placing them into a chamber then evacuate the chamber then introduce steam then re-evacuate again (col.5, lines 22-32), injecting ethylene gas into the chamber (col.5, lines 40-41), introducing an overpressure nitrogen gas into the chamber (col.5, lines 37-40), holding the items in the chamber until sterilization is reached (col.5, lines 43-45) and degassing the items (col.6, lines 35-44).

Regarding claims 2-4, 6 and 13, Popescu teaches the following: heated inert gas is nitrogen (col.5, lines 54-56), sterilant is ethylene gas (col.5, lines 40-41), evacuating the chamber after holding the product in the chamber (col.5, lines 49-51) and pulsing in heated inert gas into the chamber (col.6, lines 12-35), degassing the items by evacuating the chamber (col.6, lines 19-21), pressurizing the chamber with 3 to 50 inches of mercury with nitrogen gas (21-22), repeating until the items are degassed (col.6, lines 19-32) and the rate of degassing is in the range of 0.1 to 0.5 inches per

Art Unit: 1744

minute (col.6, lines 27-28, 0.83 Kpa/min is equivalent to 0.24 inches of mercury/min).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) in view of Vera et al (U.S.P.N. 6,440,364) and

further in view of Joslyn (U.S.P.N. 4,770,851).

Regarding claim 14, Popescu teaches the following steps in ethylene sterilization of medical items (col.1, lines 6-11): conditioning items by placing them into a chamber then evacuate the chamber then introduce steam then re-evacuate again (col.5, lines 22-32), injecting ethylene gas into the chamber (col.5, lines 40-41), introducing an overpressure nitrogen gas into the chamber (col.5, lines 37-40) at a pressure of 13 inches of mercury (col.5, lines 38-40), holding the items in the chamber until sterilization is reached (col.5, lines 43-45), evacuating the chamber to vacuum pressure values less than 1-3 inches of mercury and pulsing in heated nitrogen into the chamber (col.5, lines 53-55). Popescu fails to teach evacuating to a pressure of 1 to 3 inches of mercury and injecting the chamber with warm air. Vera teaches evacuating to a pressure of 1 to 3 inches of mercury (col.3, lines 46-48) and injecting filtered air into the chamber (col.5, lines 5-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by evacuating the chamber to pressure of 1 to 3 inches of mercury to provide an effectively low pressure sufficient to effectively remove air from the chamber (Vera, col.3, lines 44-46) and to flush the chamber with filtered air in order to perform the degassing cycle into separate chambers (Vera, col.5, lines 1-7).

Vera teaches injecting filtered air into the chamber (col.5, lines 5-11), but fails to teach injecting warm air. Joslyn teaches injecting warm air into the chamber (col.6, lines 40-43). As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a heated air

Art Unit: 1744

injection step as taught by Joslyn in order to insure that the residual concentration of ethylene oxide is kept to minimum within the sterilized load at the shortest possible time (Joslyn, table 2, columns 3-4).

Regarding claim 15, Popescu discloses that the evacuating rate during the degassing cycle is in the range of 0.1 to 0.5 inches per minute (col.6, lines 27-28, 0.83 Kpa/min is equivalent to 0.24 inches of mercury/min), but fails to teach evacuating to a pressure of 1 to 3 inches of mercury. Vera teaches evacuating to a pressure of 1 to 3 inches of mercury (col.3, lines 46-48). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by evacuating to between 1 to 3 inches of mercury as taught by Vera in order to effectively remove air from the chamber and the package (Vera, col.3, lines 44-46).

Regarding claim 16, Popescu teaches repeating the step of pulsing heated nitrogen into the chamber (col.5, lines 54-56 and col.6, lines 19-32).

7. Claims 5 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) as applied to claim 4 and further in view of Vera et al (U.S.P.N. 6,440,364), Stewart et al (U.S.P.N. 5,882,590) and Weber et al (U.S.P.N. 5,161,686).

Popescu fails to teach evacuating to a pressure of 1 to 3 inches of mercury and the use of real-time monitoring of headspace. Vera teaches evacuating to a pressure of 1 to 3 inches of mercury (col.3, lines 46-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by evacuating to between 1 to 3 inches of mercury as taught by Vera

in order to effectively remove air from the chamber and the package (Vera, col.3, lines 44-46).

Vera fails to teach the use of real-time monitoring of headspace. Stewart teaches the use of real-time monitoring (col.3, lines 19-22). Therefor, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding real-time monitoring step as taught by Stewart so that the concentration of sterilant is maintained within the required range thereby guaranteeing efficient sterilization.

Stewart fails to teach monitoring headspace. Weber teaches measuring headspace within web structures (col.12, lines 56-62) and performing headspace analysis. Therefor, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a headspace measurement step as taught by Weber in order to determine the absorbing abilities of various web materials (Weber, col.12, lines 56-59) resulting in sterilizing materials more efficiently.

Regarding claim 10, Popescu teaches degassing the items by evacuating the chamber, pressurizing the chamber with 29 inches of mercury with nitrogen and repeating the cycle (col.6, lines 19-35).

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580), Vera et al (U.S.P.N. 6,440,364), Stewart et al (U.S.P.N. 5,882,590), Weber et al (U.S.P.N. 5,161,686) as applied to claim 10 and further in view of Joslyn (U.S.P.N. 4,770,851).

Vera teaches injecting filtered air into the chamber (col.5, lines 5-11). However, Popescu, Vera, Stewart and Weber all fail to teach injecting warm air. Joslyn teaches injecting warm air into the chamber (col.6, lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a warm air injection step as taught by Joslyn in order to insure that the residual concentration of ethylene oxide is kept to minimum within the sterilized load at the shortest possible time (Joslyn, table 2, columns 3-4).

9. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580), Vera et al (U.S.P.N. 6,440,364), Stewart et al (U.S.P.N. 5,882,590), Weber et al (U.S.P.N. 5,161,686) as applied to claim 5 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

Popescu, Vera, Stewart and Weber all fail to teach evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by including the pulsing process of Kolstad in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors (Kolstad, col.5, lines 30-41) for more efficient sterilization of the contents.

10. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu

et al (U.S.P.N. 5,464,580) as applied to claim 6 and further in view of Joslyn (U.S.P.N. 4,770,851).

Popescu fails to teach injecting warm air. Joslyn teaches injecting warm air into the chamber (col.6, lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a warm air injection step as taught by Joslyn in order to insure that the residual concentration of ethylene oxide is kept to minimum within the sterilized load at the shortest possible time (Joslyn, table 2, columns 3-4).

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) as applied to claim 3 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

Popescu fails to teach evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by including the pulsing process of Kolstad in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors (Kolstad, col.5, lines 30-41) for more efficient sterilization of the contents.

Response to Arguments

12. Applicant's arguments filed on 07/11/2006 have been fully considered but they are not persuasive.

On pages 6-7 of the Remarks section, applicant argues that no precise method of monitoring the moisture content is taught in Popescu and that Popescu fails to teach or claim evacuating a single chamber. The instant claims do not include such features.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

Art Unit: 1744

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC


WILLIAM H. BEISNER
PRIMARY EXAMINER
GROUP 1744